APPENDIX B

Williams, R. B. (1997©). Epidemiological aspects of the use of live anticoccidial vaccines for chickens. VIIth International Coccidiosis Conference, 1-5 September, Keble College, Oxford, UK,, International-Journal-for-Parasitology.

This review addresses the epidemiology (epizootiology) of coccidiosis in commercial chickens with emphasis on the effects on the use of live vaccines. Surveys suggest that all 7 valid species of chicken coccidia (Eimeria acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. praecox and E. tenella) are ubiquitous. All species are pathogenic to various extents. New results are presented on the pathogenicities of E. acervulina, E. mitis and E. praecox. This review address the epidemiology (epizootiology) of coccidiosis in commercial chickens with emphasis on the effects on the use of live vaccines. Surveys suggest that all seven valid species of chicken coccidia (Eimeria acervulina, Eimeria brunetti, Eimeria maxima, Eimeria mitis, Eimeria necatrix, Eimeria praecox and Eimeria tenella) are ubiquitous. All species are pathogenic to various extents. New results are presented on the pathogeneicities of E. acervulina, E. mitis and E. Praecox. Unless ingested by chickens, oocysts in poultry-house litter may die after about 3 weeks. Oocyst sporulation may be better in drier, rather than wetter, litter. Whether sporulated or not, up to 20% of ingested oocysts may pass undamaged through a chicken's intestine. The excreted, sporulated oocysts can be immediately reingested to initiate an infection; the unsporulated oocysts can still sporulate after passing through the intestine. The seven species differ in their times of appearance in commercial flock; hence particular vaccines may be designed for rearing standard broilers for up to about 6 weeks or for breeding stock. Attenuated, precocious lines of Eimeria in vaccines have low reproductive potentials, thus avoiding crowding, developing optimally, and stimulating immune response with minimal tissue damage. Cross-immunity between Eimeria species is probably minimal. There is reciprocity between the immune status of chicken and their excretion of oocysts for each species, ensuring continual stimulation of immune responses in birds on litter. Paracox vaccine, comprising all seven Eimeria species, is shown here to stimulate immunity to each of them independently. Total oocyst accumulation in litter following Paracox vaccination at 1 week comprises a small peak of vaccinal oocysts at 2-4 weeks, then a higher peak of the local virulent population at 4-7 weeks, which rapidly wanes. The attenuated drug-sensitive vaccinal oocysts probably interbreed with the corresponding wild species, reducing both virulence and drug-resistance in the local population. Anticoccidial vaccines may not induce complete immunity in chickens with lowered immunocompetence du to stressors, including certain virai disease. Future development of live vaccines for standard broilers may be expected in the relatively short term. The useful lives of anticoccidial drugs might be extended by rotating them with live vaccines.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

David G. Richards, et al.

Appln. No.: 09/647,098 Group Art Unit: 1645

Filed: September 26, 2000 Examiner: V. Ford

For: VACCINATION MODALITIES

STATEMENT OF AVAILABILITY

Assistant Commissioner
of Patents
Washington, D.C. 20231

Sir:

We, EIMERIA PTY LIMITED, THE STATE OF QUEENSLAND THROUGH THE DEPARTMENT OF PRIMARY INDUSTRIES, and RURAL INDUSTRIES RESEARCH AND DEVELOPMENT CORPORATION, do depose, declare and state that:

We are the Assignees of the entire right, title and interest of the invention described and claimed in the above-identified application, as evidenced by the Assignment recorded on May 2, 2001, at REEL 011816, FRAME 0994.

We agree that upon allowance and issuance of the above-identified application into a United States Patent, restriction on availability of:

Eimeria maxima ARI-73/97 (Deposit No. NM 98/02796)

Eimeria acervulina ARI-77/97 (Deposit No. NM 98/02794)

Q60901

STATEMENT OF AVAILABILITY
U.S. Appln. No. 09/647,098

Eimeria necatrix MCK01 (Deposit No. NM 98/02797)

Eimeria necatrix ARI-MEDNEC$_3$+8 (Deposit No. NM 99/02118)

Eimeria tenella ARI-11/98 (Deposit No. NM 98/02795)

which were designated in the specification of the above-identified application and deposited at the Australian Government Analytical Laboratories, located at 1 Suakin Streeet, Pymble, New South Wales, 2073, Australia, on March 17, 1998 (Deposit Nos. NM 98/02796, NM 98/02794, NM 98/02797, and NM 98/02795), and March 30, 1999 (Deposit No. NM 99/02118), will be irrevocably removed.

We agree that the above-identified organisms designated in the above-identified application will be maintained for a period of 30 years or 5 years after the last request for the deposit or for the effective life of any patent which issues on the above-identified application, whichever is longer;

We agree that if the deposits become non-viable, they will be replaced; and

We also assure access to the deposits to one determined by the Commissioner to be entitled thereto under 37 C.F.R. §1.14 and 35 U.S.C. §122.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Q60901

STATEMENT OF AVAILABILITY
U.S. Appln. No. 09/647,098

Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

EIMERIA PTY LIMITED

Date: 4 December 2002

Name: _____
Name: D.G. RICHARDS
Title: Director Eimeria P/L, Inventor of steahs.

THE STATE OF QUEENSLAND THROUGH THE DEPARTMENT OF PRIMARY INDUSTRIES

Date: 9/12/02

Name: _____
Name: Terry Johnston
Title: Acting Director General DPI, Qld

RURAL INDUSTRIES RESEARCH AND DEVELOPMENT CORPORATION

Date: 17-12-02

Name: _____
Name: S.E. Hearn
Title: Managing Director.